Questions for Consideration

Panel Discussion # 3

Question #1b

- Are tests currently available that can replace in vivo tests?
- The polio neurovirulence story although testing for the active agent is instructive in how difficult change can be.

Question #2

- Are we adequately testing for the spectrum of viral agents that might be found in tissue culture?
- In investigational lots exogenous contamination (usually bacterial) is the most common reason for disqualification. Are the assays for this adequate?

Question # 3

- Do the test for vaccine safety (active component of the vaccine) overlap or give additional information on substrate safety?
- Are the methods to inactivate active component adequate?

Question # 4

- In a vaccine developmental pathway safety testing can introduce substantial delay. This is as much of a problem as volume of pool consumed in testing.
- Is there a way of shortening this process?

Question #4

- Is there a synergy in the work on biosensors and biodefense that can be used to assure substrate safety?
- Do molecular methods, however sensitive test an adequate volume of vaccine or cell substrate?